UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,721	05/02/2001	John Charles Brennand	1991-196	3814

6449 7590 12/16/2002

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/16/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/845,721	BRENNAND ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *3-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group II, claims 1 and 2, drawn to a method of screening for antagonistis of GPR22 capable of being an appetite control agent in Paper No.: 9 (10/7/02) is acknowledged.

Claims 3-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: A method of screening for antagonistis of GPR22 capable of being an appetite control agent.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1and 2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are directed to a method of screening for antagonists of GPR22 capable of being an appetite control agent. It is alleged that GPR22 protein belongs to G

protein-coupled receptor family (GPCR). These claims are drawn to an invention with no apparent or disclosed patentable utility. The applicant claims that the mRNA coding GRP22, is differentially expressed in rodent appetite/obesity model. Thus, they assert that peptidic and non-peptidic compounds that are capable of modulating the biological activity of GPR22, will have utility in controlling food intake and metabolic process (page: 2, lines 1-4). There are no RNA or protein blots to indicate the expression profile. In addition, the instant application does not disclose the biological role of this protein or its significance. Novel biological molecules lack well-established utility and must undergo extensive experimentation.

The applicant states that the human GPR22 is a receptor protein with no known physiological ligand. Thus, it is termed in the art as an "orphan receptor" (page: 2, lines 5-6). The receptor with closest identity is the receptor for cholecystokinin-B, with which it shares 34% identity in the transmembrane domains. Applicant's claim that the instant protein belongs to a G protein-coupled receptor family is presumably because of sequence homology between the instant invention (human GPR22 protein sequence) and various known G protein-coupled receptors. However, Ji et al. (J. Biol. Chem. 273 (28): 17299-17302) indicate that G protein coupled receptors are classified into over 100 subfamilies according to sequence homology, ligand structure and receptor function. A substantial degree of amino acid homology is found among members of a particular subfamily, but comparison between subfamilies show significantly less or no similarity. Mutant G-protein coupled receptors are incapable of binding ligand or generating normal signals, constitutively generate signals, or are not appropriately expressed on the cell surface (page: 17299, paragraphs 1 and 2). Also, "an increasing number of G protein-coupled receptor subfamilies show diverse modes of ligand binding, signal

generation, transmembrane signal transduction, and signal transfer to various cytoplasmic signal molecules other than G-protein" (page: 17302, paragraph 4). Furthermore, since the specification does not disclose any methods or working examples that demonstrate the polynucleotide and polypeptide of the instant application exhibit similar activities of other G protein-coupled receptors, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application as a G protein-coupled receptor. Additionally, the specification of the instant application does not teach the skilled artisans which domains of human GPR22 protein sequence are structurally related to other G protein-coupled receptors. One skilled in the art would not know the utility and function of human GPR22 protein, even if it was a putative G protein coupled receptor because, as discussed in the related art above and the specification of the instant application, neither the prior art nor the specification provides for the physiological significance of the claimed receptor. Furthermore, as described above, the natural ligand for GPR22 is not yet known. As described by the Ji et al. reference, there are several distinct modes for high affinity ligand binding to the TM core exclusively (photon, biogenic amines, nucleosides, eicosanoids, and moieties (lysophosphatidic acid and sphingosine 1-phosphate) of lipids), to both the core and exoloops (peptides $\leq$ 40 amino acids), to exoloops and N-terminal segment (polypeptides In the absence $\leq$ 90 amino acids), or exclusively to the N-terminal segment (glycoproteins $\geq$30 kDa). The distinction between ligand binding and receptor activation is supported by the existence of antagonists that competitively inhibit agonist binding (page: 17300, paragraph 3). Thus in the absence of the natural ligand, it is unclear how one can ascribe the utility to compounds capable of being antagonists of GPR22.

There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that of which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed "real-world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility," "[u]nless and until a process is refined and developed to this point - where specific benefit exists in currently available form - there is insufficient justification for permitting an applicant to engross what may prove to be a broad field," and "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a method of screening for antagonistis of GPR22 capable of being an appetite control agent, which have a yet undetermined function or biological significance. Applicants have disclosed the cDNA sequence (SEQ ID NO: 1) and amino acid (SEQ ID NO: 2) of GPR22. They also claim that the instant RNA is expressed in discrete brain regions including thalamus, caudate, frontal cortex and putamen based on O'Dowd et al., (1997) reference (page: 2, lines 9-10). However, there is no actual and specific significance, which can be attributed to said polypeptides

and the polynucleotides identified in the specification or the art of record, except the prophetic recitation of potential uses, which include the use of this GPR22 protein and the nucleotides in screening assays for antagonists that are capable of being an appetite control agent (pages: 2-3). For this reason, the instant invention is incomplete. Since, neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed receptor or its ligand, there is no immediately obvious patentable use for it. In addition, the instant specification does not disclose a "real-world" use for said polypeptides and polynucleotides, except the prophetic recitation of potential uses, which include possible use in screening for antagonists of GPR22. Also, there are no working examples that demonstrate any specific utility. Thus, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. Therefore, since the peptide of the invention is not supported by a specific and substantial asserted utility or a well established utility, then the composition comprising the polypeptide and a carrier also are not supported by a specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1and 2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and

substantial asserted utility or a well established utility for the reasons set forth above (Paragraph 4), one skilled in the art clearly would not know how to use the claimed invention to identify the antagonists of GPR22. Furthermore, even if utility was established it will not be enabled for reasons set forth above. In addition, it is unclear how one of ordinary skilled in the art would conduct appetite control test procedures. Since there is no guidance provided in the specification, it would require trial and error experimentation to identify the test procedures. Furthermore it is not clear how one will identify the active compounds for use as an appetite control agent. The specification fails to provide any guidance regarding the ligand binding to GPR22, it would require undue experimentation to identify antagonist of GPR22. Therefore, claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claims 1 and 2 are rejected as being vague and indefinite in the recitation of the term "G protein coupled receptor GPR22". The protein of interest is described by an arbitrary protein name. It is unclear from which vertebrate species the nucleic acid

encoding the said protein was isolated. Applicant should particularly point out and distinctly claim the GPR22 by claiming structural characteristics associated with the protein (e.g. amino acid sequence, molecular weight, etc.). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is. Applicant is required to provide SEQ ID Nos to isolated nucleic acid and protein sequences.

6b. Claims 1 and 2 are rejected as being vague and indefinite in the recitation of the term "appetite control test procedures". It is unclear what these procedures are.

6c. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: It is not clear how one would identify antagonist of GPR22 and then proceed to use it as agents to control appetite.

7. No Claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D., whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for

the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
December 13, 2002

JEFFREY STUCKER
PRIMARY EXAMINER